

## EXHIBIT B

## ATTACHMENT A

This statement reflects facts as to which Pfizer and the United States agree are true and accurate. It does not contain all of the United States' factually-based contentions regarding Pfizer's marketing of Zyvox, nor does it contain all of Pfizer's responses to those allegations:

1. Zyvox (linezolid) is an antibacterial agent that is approved by the FDA to treat certain types of infections including, among other approved indications, nosocomial pneumonia caused by methicillin-resistant *Staphylococcus aureus* ("MRSA") and complicated skin and skin structure infections ("CSSSIs") due to MRSA.
2. Although Zyvox is approved to treat these indications, it has not been demonstrated by substantial evidence to be superior to the primary competitor drug for those indications: vancomycin, an antibiotic that has been on the market for nearly fifty years.
3. On July 20, 2005, the FDA sent Pfizer a Warning Letter ("Warning Letter") regarding a journal advertisement for Zyvox. In this Warning Letter, the FDA stated that Pfizer's advertisement misbranded Zyvox by making misleading and unsubstantiated implied superiority claims, claims that broadened the indications of Zyvox, and omitted important safety information.
4. The FDA stated in the Warning Letter that the journal advertisement implied that Zyvox is superior to vancomycin for the treatment of nosocomial pneumonia caused by MRSA. Specifically, the FDA Warning Letter objected to the advertisement's use of certain retrospective analyses of head-to-head clinical trials of linezolid and vancomycin. The FDA stated that these analyses were not prospectively designed or sufficiently powered to demonstrate statistically significant differences in treatment groups. Thus, the FDA stated that the superiority of Zyvox for the treatment of nosocomial pneumonia caused by MRSA had not been demonstrated by substantial evidence and that the advertisement was therefore misleading.
5. The FDA stated that Pfizer's advertisement misbranded Zyvox in violation of 21 U.S.C. 352(n) & 321(n) and FDA implementing regulations and requested that Pfizer cease dissemination of the journal advertisement and other promotional materials containing similar statements.
6. After receiving the Warning Letter, Pfizer responded to the FDA, taking the position that it did not believe that the journal advertisement made an improper superiority claim. However, Pfizer informed the FDA that, in response to the FDA's concerns, Pfizer would cease use of the journal advertisement in question. Further, Pfizer informed the FDA that all other Zyvox promotional materials had been reviewed to identify other items that could raise similar concerns, and that steps had been taken to discontinue or appropriately revise any promotional materials that could potentially be misinterpreted in a similar manner. Pfizer also

informed the FDA that it was instructing its sales force that materials containing information that the FDA stated constituted an implied superiority claim could no longer be used. Pfizer also advised its sales force to discontinue using certain identified promotional materials and that sales representatives would be provided with replacement pieces.

7. In addition, at the FDA's request, Pfizer agreed to publish a corrective advertisement in February 2006, which was entitled "IMPORTANT CORRECTION OF DRUG INFORMATION ZYVOX." In this corrective advertisement, Pfizer noted that the FDA had objected to the presentation, in its previous advertisement, of clinical data that showed a more favorable comparison of Zyvox to vancomycin than was shown in the data included in the the Zyvox label, which states that 57% of Zyvox patients and 60% of vancomycin patients in the clinically evaluable population were cured of MRSA. Further, the label reflects that 59% (13/22) of Zyvox patients and 70% (7/10) of vancomycin patients with microbiologically-confirmed MRSA at baseline were clinically cured.
8. Despite notifying its sales force that it should cease using promotional materials that raised concerns of the type identified in the FDA Warning Letter, Pfizer did not provide adequate guidance to its sales force regarding what statements were permissible concerning data from head-to-head trials and retrospective analyses and what promotional statements were not permitted.
9. As a result, Pfizer's sales personnel thereafter continued to make claims to physicians that Zyvox was superior to vancomycin for certain patients with MRSA, which included the claim that Zyvox would have a higher cure rate, and would save more lives, despite the fact that these claims were inconsistent with the FDA's Warning Letter and Zyvox's FDA approved label, and which were inconsistent with the manner in which Pfizer, after the receipt of the Warning Letter, agreed to present the clinical data cited by the FDA.
10. Moreover, certain Pfizer sales managers, including a regional manager and a headquarters-based vice president, were aware of and, in certain cases, encouraged a sales message that Zyvox was superior to vancomycin for certain patients, despite their knowledge of the FDA Warning Letter and the issues it raised.